JUN - 1 2004

K040659

510(k) Summary

McCue Energist ULTRA™ Pulsed Light System

This 510(k) summary of safety and effectiveness for the McCue Energist ULTRA pulsed light system by McCue Plc is submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990 and follows the Office of Device Evaluation (ODE) guidance concerning the organisation and content of a 510(k) summary.

Applicant:	McCue Plc
Address:	Unit 27 Solent Indust. Estate, Hedge End, Southampton. SO23-2FY. England
Contact Person:	Steven Peach (General and Technical Manager)
Telephone:	44 1489 795668
Preparation Date:	19th February 2004
Device Trade Name:	McCue Energist ULTRA™
Common Name:	Intense Pulsed Light System
Classification Name:	Laser surgical instrument for use in General and Plastic surgery and Dermatology 21 CFR 878.4810 Product Code: GEX Panel: 79
Legally-Marketed Predicate Devices:	The McCue Energist ULTRA™ is substantially equivalent to the following currently marketed devices: Lumenis, Inc. IPL Quantum, K020839 Radiancy, Inc. SpaTouch, K020856 Radiancy, Inc. Skin Station, K030897 Palomar, Inc. EsteLux, K020453, K020941 Alderm/MBC, Prolite/Plasmalite, K013365, K022568, K023081
System Description:	The McCue Energist ULTRA™ is a light-based medical device that delivers a beam of pulsed non-ionising radiation in the region of 530nm to 950nm. The system has been designed to be compact and self-contained that includes: • Control console unit • Display panel • Power supply • Cooling system • Removable handpiece with integrated switch, lamp, filter and glass coupling block
Intended Use:	The McCue Energist ULTRA™ VPL Intense Pulsed Light System is intended for permanent hair reduction. It is also indicated for photocoagulation of dermatological vascular lesions, photothermolysis of blood vessels and the treatment of benign pigmented lesions. • Intense Pulsed light Energy / wavelengths (530 – 950nm) The 530-950nm intense pulsed wavelengths are indicated for : The treatment of benign pigmented epidermal and cutaneous lesions including warts, scars and striae. The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, melasma, angiomas and spider angiomas, poikiloderma of Civatte, leg veins, facial veins and venous malformations.

I201

	• Intense Pulsed light Energy / wavelengths (610 – 950nm) The 610-950nm intense pulsed wavelengths are indicated for : The removal of unwanted hair from all skin types, and to effect stable long-term or permanent[*1] hair reduction in skin types I - V through selective targeting of melanin in hair follicles. [*1] Permanent hair reduction is defined as a long-term stable reduction in the number of hairs regrowing after a treatment regimen.
Performance Data:	The differences in specifications of the McCue Energist ULTRA™ and the predicate devices do not result in different performance or raise new questions of safety and efficacy.
Conclusion:	Based on the foregoing, the McCue Energist ULTRA™ system is substantially equivalent to the legally-marketed predicate devices.

I202

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 1 2004

McCue PLC
c/o Mr. John W. Howlett
British Standards Institution
Maylands Avenue
Hemel Hempstead
Herts HP2 4SQ
United Kingdom

Re: K040659
Trade/Device Name: McCue Energist ULTRA™ VPL Intense Pulsed Light System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: May 12, 2004
Received: May 20, 2004

Dear Mr. Howlett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040659

Device Name: McCue Energist ULTRA™ VPL Intense Pulsed Light System

Indications for Use:

The McCue Energist ULTRA™ VPL Intense Pulsed Light System is intended for permanent hair reduction. It is also indicated for photocoagulation of dermatological vascular lesions, photothermolysis of blood vessels and the treatment of benign pigmented lesions.

- Intense Pulsed light Energy / wavelengths (530 – 950nm)

  The 530-950nm intense pulsed wavelengths are indicated for :

  The treatment of benign pigmented epidermal and cutaneous lesions including warts, scars and striae.

  The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, melasma, angiomas and spider angiomas, poikiloderma of Civatte, leg veins, facial veins and venous malformations.

- Intense Pulsed light Energy / wavelengths (610 – 950nm)

  The 610-950nm intense pulsed wavelengths are indicated for :

  The removal of unwanted hair from all skin types, and to effect stable long-term or permanent[*1] hair reduction in skin types I - V through selective targeting of melanin in hair follicles.

[*1] Permanent hair reduction is defined as a long-term stable reduction in the number of hairs regrowing after a treatment regimen.

Prescription Use X
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

D2

510(k) Number K040659